

Notice of Allowability

Application No.

09/756,551

Examiner

Joseph T. Voitach

Applicant(s)

MORROW ET AL.

Art Unit

1632

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to April 5, 2004.
2. ☒ The allowed claim(s) is/are 49-63.
3. ☒ The drawings filed on 29 December 2003 are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☐ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☒ Information Disclosure Statements (PTO-1449 or PTO/SB/08),
Paper No./Mail Date _____
4. ☐ Examiner's Comment Regarding Requirement for Deposit
of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☒ Interview Summary (PTO-413),
Paper No./Mail Date _____.
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____.

DETAILED ACTION

This application is a continuation of 09/376,184, filed August 17, 1999, now abandoned, which is a continuation of 08/987,867, filed December 9, 1997, now patent number 6,063,384, which is a continuation of 08/389,459, filed February 15, 1995, now patent number 5,817,512, which is a continuation of 08/087,009, filed July 1, 1993, now abandoned.

Applicants' amendment filed April 5, 2004, has been received and entered. Claims 49, 55 and 61 have been amended. A notice of non-compliant amendment was mailed March 23, 2004 because claims 1-48 were not listed. It is noted that this was in error because cancelled claims need only be listed and do not require that the text be provided.

Applicants' amendment filed December 29, 2003 has been received and entered. The drawing has been entered. The CRF has been processed and the new sequence listing has been entered (January 12, 2004). The application is now in sequence compliance.

Claims 49-63 are pending and currently under examination as they are drawn to a method of expressing a foreign gene in a cell both *in vivo* and *ex vivo*.

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

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Authorization for this examiner's amendment was given in a telephone interview with Kate H. Murashige on June 3, 2004.

The application has been amended as follows:

In the claims:

49. A method for expressing a non-polio nucleotide sequence in a cell comprising contacting [the] a cell[, in a physiologically acceptable carrier,] with an amount of a composition effective to result in [said] expression of a non-polio nucleotide sequence, said composition comprising a recombinant polio virus nucleic acid having a non-polio nucleotide sequence encoding, in an expressible form, a gene product substituted for at least a portion of the P1 capsid precursor region of the poliovirus genome, under conditions appropriate for introduction of the recombinant poliovirus nucleic acid into the cell, thereby generating a modified cell which expresses [a] said gene product encoded by said non-polio nucleotide sequence.

62. The method of claim 61 [60] wherein the viral gene is an HIV gene.

In the specification:

On page 6, line 35, after the end of the sentence add:

--In figure 23B, Thr-Thr-Ala-Lys-Leu-Thr (SEQ ID NO: 24) is the polypeptide sequence at the transition between the encoded signal sequence and CEA. In figure 23C, Met-Gly-Leu-Gu-Lys (SEQ ID NO: 25) is the polypeptide sequence at the transition between the encoded polio and CEA sequences, and Ile-Tyr-Val-Thr-Lys-Asp-Leu-Thr-Thr-Tyr-Gly (SEQ ID NO: 26) is the polypeptide sequence at the transition between the encoded CEA and 2A cleavage sequences.--

Reasons for Allowance

The following is an examiner's statement of reasons for allowance:

With regard to the rejection made under 35 U.S.C. 112, second paragraph, the amendment to the claims to delete a 'foreign protein' and insert a "non-polio nucleotide sequence" has addressed that basis of the rejection, and the rejection is withdrawn. With regard to the obviousness-type double patenting rejections of claims 49-57, 61 and 62 over U.S. Patent No. 6,063,384, and claims 49-63 are rejected over U.S. Patent No. 5,817,512, the terminal disclaimers filed December 29, 2003 have been approved and entered, obviating the basis of the rejections. The amendments entered by the Examiner were made for consistency and clarity to incorporate specific antecedent basis from the preamble to the method steps of the claim.

The product used in the claimed method has been allowed in US Patent 5,817,512, and a method to stimulate an immune response to a protein produced by the vector has been allowed in US Patent 6,063,384 ('384). Similar to the method of '384, the present method is now drawn more generally to providing expression of a protein in a cell.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph Woitach whose telephone number is (571) 272-0739.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached at (571) 272-0734.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group analyst Dianiece Jacobs whose telephone number is (571) 272-0532.

Joseph T. Voitach


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